

Dockets Management Branch (HFA-305)
Docket No. 98-N-1265
Food and Drug Administration
5600 Fishers Lane Room 1061
Rockville, MD 20857

Nancy Shulman
Shoals Vision Clinic
1202B Woodward Ave.
Muscle Shoals, AL 35661

(256) 381-0100
Email Nancy ~~PS~~ @AOL.com

8560-99 JUN -1 21:36
I OPPOSE THE DRAFT M.O.U. being proposed by the FDA. In particular, I
OBJECT to the definition of "inordinate amount" which restricts the availability and
the right to obtain necessary compounded medications by limiting the number of
prescriptions that can be shipped across state lines from specialized
compounding pharmacies.

Nancy P. Shulman
Signature

5-20-99
Date

Comments: Please don't allow this Draft M.O.U. to pass.
My very sanity depends on getting specially compounded
hormones. I live in a small town & found NO ONE
here who could compound this well. ! Please, PLEASE
Reconsider !
NS

98N-1265

C2942

May 15, 1999

To Whom it May Concern:

I am writing with regard to Docket No. 98-N-1265.

I have been using a specially compounded gel since January of 1998 for Hormone Replacement Therapy.

I feel I would have lost my mind by now if I couldn't have found something that made me feel better.

I have endometriosis and it was necessary for me to have a total hysterectomy and removal of my ovaries in May of 1996 to help control the disease and end my pain. My body has some type of autoimmune problem, and I have had numerous troubles taking drugs throughout my life. My body didn't respond well at all to the synthetic pills, patches or anything oral that I used to try and control my severe surgical menopause symptoms. I even tried several compounded medications from a local pharmacy with little success.

I feel that the ability to use a compounded drug has saved my life, sanity, and still allowed me to work.

I do not understand where or why there is a problem in shipping reasonable amounts of prescription drugs across state lines. It seems as though this is an effort for the big drug companies to lobby and limit what we as American citizens should be entitled to use.

I can assure you that I and many women I have met on the internet will fight this as much as possible. There are many women who don't react well to synthetic drugs, or the horse pee drug that has been crammed down our throats for years. The side effects for me from that drug are numerous and dangerous to my well being, as well as my strong feelings about Equine Abuse.

I will be on the steps of the Capitol to demonstrate against this law if needed.

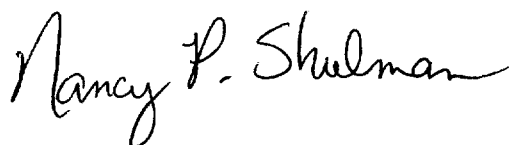
Please consider what is best for the general population, not what is best for big business. We are human beings, just trying to cope with some very difficult life problems, and taking away something we can use, that makes us feel some better is ludicrous.

I will consider moving to the state that my compounding pharmacy is in if I have no other recourse, it means that much to me. I won't do it without a fight, or without a major lawsuit.

Please reconsider this MOU regarding "Inordinate amount" which could restrict my access to such a helpful drug.

Sincerely,

Nancy Pursley Shulman

A handwritten signature in cursive script that reads "Nancy P. Shulman". The signature is written in dark ink and is positioned to the right of the typed name.

Nancy Shulman
Shoals Vision Clinic
1202B Woodward Ave.
Muscle Shoals, AL 35661

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Food & Drug Administration
5600 Fishers Lane Room 1061

Rockville, MD 20857

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